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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/884,894	06/19/2001	Daniel J. O'Sullivan	110.01290101	1710

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[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1651

DATE MAILED: 05/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/884,894	Applicant(s) O'Sullivan et al.
	Examiner Deborah Ware	Art Unit 1651
<i>-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --</i>		
Period for Reply		
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.		
<p>- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.</p> <p>- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.</p> <p>- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.</p> <p>- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).</p> <p>- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).</p>		
Status		
1) <input checked="" type="checkbox"/> Responsive to communication(s) filed on <u>Feb 21, 2003</u>		
2a) <input checked="" type="checkbox"/> This action is FINAL . 2b) <input type="checkbox"/> This action is non-final.		
3) <input type="checkbox"/> Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11; 453 O.G. 213.		
Disposition of Claims		
4) <input checked="" type="checkbox"/> Claim(s) <u>9-15 and 20-44</u> is/are pending in the application.		
4a) Of the above, claim(s) <u>9-15, 20-28, 30-40, and 42</u> is/are withdrawn from consideration.		
5) <input type="checkbox"/> Claim(s) _____ is/are allowed.		
6) <input checked="" type="checkbox"/> Claim(s) <u>29, 41, 43, and 44</u> is/are rejected.		
7) <input type="checkbox"/> Claim(s) _____ is/are objected to.		
8) <input type="checkbox"/> Claims _____ are subject to restriction and/or election requirement.		
Application Papers		
9) <input type="checkbox"/> The specification is objected to by the Examiner.		
10) <input type="checkbox"/> The drawing(s) filed on _____ is/are a) <input type="checkbox"/> accepted or b) <input type="checkbox"/> objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).		
11) <input type="checkbox"/> The proposed drawing correction filed on _____ is: a) <input type="checkbox"/> approved b) <input type="checkbox"/> disapproved by the Examiner. If approved, corrected drawings are required in reply to this Office action.		
12) <input type="checkbox"/> The oath or declaration is objected to by the Examiner.		
Priority under 35 U.S.C. §§ 119 and 120		
13) <input type="checkbox"/> Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) <input type="checkbox"/> All b) <input type="checkbox"/> Some* c) <input type="checkbox"/> None of: 1. <input type="checkbox"/> Certified copies of the priority documents have been received. 2. <input type="checkbox"/> Certified copies of the priority documents have been received in Application No. _____. 3. <input type="checkbox"/> Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). *See the attached detailed Office action for a list of the certified copies not received.		
14) <input checked="" type="checkbox"/> Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e). a) <input type="checkbox"/> The translation of the foreign language provisional application has been received.		
15) <input type="checkbox"/> Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.		
Attachment(s)		
1) <input type="checkbox"/> Notice of References Cited (PTO-892)		
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)		
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). <u>16</u>		
4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____		
5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)		
6) <input type="checkbox"/> Other: _____		

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Claims 9-15 and 20-44 are now pending.

Further, the extension of 1 month of time is acknowledged. Furthermore, the Disclosure Statement filed February 21, 2003, has been received and the fees charged to Applicants' designated deposit account(s). The references submitted therewith have been considered as indicated on the enclosed PTO-1449 Form. The amendment filed February 21, 2003, has been received and entered. Further, Applicant's comment regarding 35 USC 112, second paragraph rejections in an Action dated January 11, 2002 is noted, and Applicant's understanding is correct.

1. Claims 9-15, 20-28, 30-40 and 42 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention(s), there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No.

12.

2. Claims 29, 41 and newly added claims 43-44 are examined on the merits.

3. This application contains claims 9-15, 20-28, 30-40 and 42 drawn to an invention nonelected with traverse in Paper No. 12. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. The amendment filed February 21, 2003, is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall

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introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: changing "decreased" to "increased" at the paragraph beginning at page 11, lines 12, since it is unclear that certain conditions for inhibition can decrease doubling time in the absence of appropriate nutrient requirements, thus, without supporting literature to back up Applicant's viewpoint it can not be determined that this change is not new matter since no prior support in the instant disclosure is noted by Applicant.

Applicant is required to cancel the new matter in the reply to this Office Action.

5. Claim 29, 41 and 43-44 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for *Bifidobacterium* strains RecB1, strain RecB4, strain J1, strain J2, strain J4, strain P1, strain 6A or strain 10A, **does not reasonably provide enablement for any and all strains of *Bifidobacterium*.** The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, **to carry out and practice the invention commensurate in scope with these claims.** The unpredictability in the microbiological arts is very high and one of skill in the art would not be capable of predicting which *Bifidobacterium* strain produces a siderophore. Therefore, **undue burden of experimentation** would be necessary for one of skill to determine which *Bifidobacterium* strain capable of secreting a siderophore for use in a composition as claimed. Although methods of screening bacteria are conventional in the art, it is not conventional to screen for *Bifidobacterium* strains that secrete siderophores. Therefore, one of skill would not be capable of predicting the appropriate strain of *Bifidobacterium* for use in the claimed composition. Thus, the claim should

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be limited to the specific strains that secrete a siderophore as disclosed in the specification at page 7, lines 10-16. **As evidence to support the unpredictability in the art the Yildrim reference cited below as art against the claim clearly teaches that not all strains of Bifidobacterium secrete or form siderophores (i.e. peptide compounds). It is believed by the examiner that each of the factors as discussed above have been adequately presented to show the claims lack enablement for the reasons discussed supra. The prior art clearly shows that not all strains are capable of producing the siderophores as defined by the instant specification at page 8. The undue burden of experimentation to select for appropriate strains which can produce siderophores is very high, because the cited prior art clearly shows that not all strains can produce siderophores, although the prior art does teach strains that do produce siderophores. It is not the position of the examiner that one of skill in the art can not determine if a Bifidobacterium secretes a siderophore but it is the level of unpredictability that dictates the amount of experimentation necessary to determine if a particular strain does indeed secrete a siderophore.**

The claims not enabled for the scope claimed herein for these reasons and those of record.

6. Claim 29, 41 and 43-44 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Yildirim et al, for those reasons of record.
7. Applicant's arguments filed February 21, 2003, have been fully considered but they are not persuasive. The rejection is reiterated below for all newly rejected claims are answers to Applicant's arguments follow:

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Claims are drawn to a composition comprising a Bifidobacterium that secretes a siderophore, used as a probiotic and combinable with a food.

Yildirim et al. teach a food biopreservative comprising bacteriocin that are secreted by Bifidobacterium. Note the abstract and at page 47, col. 1, all lines, and also col. 2, all lines, also note on page 48, col. 1, all lines. A specific strain is disclosed as being the only one that secretes a siderophore. See Material and Methods, of page 47, col. 2, all lines. At page 48, clear zones of inhibition of other bacteria growth because of the presence of siderophore of the Bifidobacterium strain are noted.

The claims appear to be identical to the disclosure of the cited reference and is therefore, considered to be anticipated by the teachings therein. The identical composition is disclosed, however, in the alternative that there is some difference between the reference and the claimed subject matter due to some unidentified claimed characteristic for which is not disclosed then such difference is considered to be so slight as to render the claim *prima facie* obvious over the cited reference. It would have been obvious to one of ordinary skill in the art to provide a composition comprising a whole Bifidobacterium that secretes a siderophore as the reference clearly teaches that such strains thereof can produce or form siderophores which are peptide compounds that are detected by their ability to inhibit the growth of other bacteria. The reference clearly teaches such peptide compounds and the inhibition of growth of indicator strains which is by Applicant's own disclosure an indicator that a siderophore is produced or formed by Bifidobacterium. It is believed to be an inherent feature of the reference that the whole

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Bifidobacterium secretes a siderophore and this being taught by the reference that the same would be comprised by a composition as also taught by the cited reference. However, if there is a difference between the reference and the claimed subject matter regarding this feature then the whole bacterium in the composition would have been expected to secrete a siderophore as claimed herein. The claims in the alternative are at least *prima facie* obvious over the cited reference. The instant specification, at page 8, disclose that a siderophore refers to a compound that is secreted by a microbe that can be a peptide or other organic material., note page 8, lines 23-24. Applicant's claims are not so limited to which microorganisms are inhibited by the siderophore. However, the cited reference clearly teaches that *Micrococcus* is inhibited by the siderophore disclosed by Yildirim. Note page 47, col. 2, all lines. Thus, it is believed by the examiner that the siderophore disclosed by Yildirim et al. does have the same properties as claimed herein or such properties are inherent to the siderophore disclosed by Yildirim et al. However, even if each and every element is not disclosed and there is some difference then such difference is so slight as to render the siderophore obvious over the teachings of Yildirim et al. The teachings of Yildirim clearly teach, or at least suggest, the siderophore to be useful as a probiotic since it inhibits the growth of pathogens and spoilage organisms which is a typical use of probiotics. Also the disclosed siderophore is combinable with food as disclosed by Yildirim et al. Therefore, the difference between the claimed siderophore and the disclosed one can not be so great as to render it unobvious since both are used in the same manner. Based on Applicant's teachings that their siderophore is a compound obtained or secreted by Bifidobacterium it is clear

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from the art that and Applicant's own disclosure that there is no significant difference between the two. Thus, the rejection is maintained.

8. Claims 29, 41 and 43-44 are rejected under 35 U.S.C. 102(b) as being anticipated by Nisbet et al. (US Pat. No. 5,340,577) for reasons of record.

Claims are discussed above.

Nisbet et al. teach a composition comprising a Bifidobacterium that secretes a siderophore since the cited disclosure clearly teaches that Salmonella is inhibited by the composition of which contains Bifidobacterium. Therefore a siderophore is present in the composition. Note the abstract and col. 12, lines 65-69. All of the bacteria in the composition are taught to produce organic acids and bacteriosins but none of which would be effective against each other. However, the composition for which promotes production of a siderophore per se does inhibit the indicator strain Salmonella. Note col. 3, lines 30-57 and the inhibition is enhanced by a composition comprising Enterococcus and Bifidobacterium, note col. 4, lines 15-17. Also at col. 2, lines 45-65, a probiotic and combination with a food is disclosed.

The claims are identical to the disclosure of Nisbet et al. and is therefore, considered to be anticipated by the teachings therein. Secretion of a siderophore by Bifidobacterium is inherent to the teachings of the reference with respect to the enhanced inhibition of Salmonella wherein the composition comprises Bifidobacterium. Therefore, the Salmonella being an indicator strain disclosed by Applicant's own specification, page 6, lines 1-5, of which indicates a Bifidobacterium that secretes a siderophore, thus, the reference clearly teaches such bacterium

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that secretes a siderophore based upon the inhibition of *Salmonella* and the enhanced inhibition obtained when the probiotic composition comprises *Bifidobacterium*. Therefore, the siderophore is inherent to the teachings of the cited reference. The argument that Nisbet do not teach a composition including just *Bifidobacterium*, etc., is noted, however, the claims are not so limited either. The point that other bacteria would be inhibited if Nisbet taught a siderophore is noted, however, Applicants claims are not so limited to which type of bacteria their siderophore inhibits. Nisbet for reasons of record is believed by the examiner to secrete a siderophore, based upon how it is used. Applicant's own claims newly require its siderophore to be useful as a probiotic, therefore, there is not enough evidence presented which shows that the *Bifidobacterium* of Nisbet does not secrete a siderophore. The rejection is thus, being maintained.

9. Claims 29, 41 and 43-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nisbet et al. in view of Yildirim et al., both discussed above.

Claims are discussed above.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to provide for the composition as disclosed by Nisbet et al. comprising a *Bifidobacterium* strain that secretes a peptide compound (i.e. siderophore) as disclosed by Yildirim. The composition is clearly suggested by the combination of the cited references if not taught by the cited references individually. Clearly one of skill would have been motivated to provide for a composition comprising a *Bifidobacterium* that secretes a siderophore. A

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siderophore is clearly taught, or at least suggested, by the cited combination of references. The claims are at the very least *prima facie* obvious over the cited references applied as a combination. For reasons of record and as discussed above it is believed that one of skill would have been motivated to provide for siderophores from *Bifidobacterium* for use a probiotic and also to provide for a composition containing a siderophore and food. The cited prior art clearly teach, if not suggest, these limitations. One of skill in the art would have expected successful results since the art recognizes their use as probiotics and because *Bifidobacterium* strains can secrete siderophores, which are peptide compounds. The claims remain *prima facie* obvious.

Claims 29, 41, and 43-44 fail to be patentably distinguishable over the state of the art discussed above. Therefore, the claims are properly rejected. Applicants' comment on previous statement at page 7 of last action is noted, and they are correct. The reference to "All" was with respect to art rejected claims as discussed in the last action, note the phrase "discussed above and cited" phraseology. Thus, indeed no non-examined claims are intended to be included by such statements herein and of record..

The remaining references listed on the enclosed PTO-892 and/or PTO-1449 are cited to further show the state of the art.

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

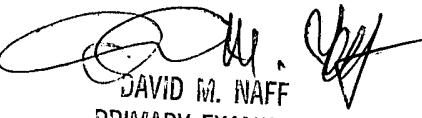
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is (703) 308-4245. The examiner can normally be reached on Mondays to Fridays from 9:30AM to 6:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn, can be reached on (703) 308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


Deborah K. Ware

May 17, 2003


DAVID M. NAFF
PRIMARY EXAMINER
ART UNIT 1651
1651